

**Remarks**

Prior to this Amendment, claims 21-57 were pending. By this Amendment, claim 47 has been canceled and new claims 58-61 have been added. Accordingly, claims 21-46 and 48-61 are now pending.

Claims 29 and 53 have been amended. Claim 29 has been amended to add a period. Claim 53 has been amended to explicitly state that the immunization leads to the reduction in incidence of mastitis.

Support for new claims 58 and 59 is found in the specification at page 23, lines 2-3: “No unfavorable reactions resulting from the vaccine's use have been reported;” page 23, lines 14-15: “No unfavorable reactions in animals receiving the product have been reported;” page 20, line 1: “No injection reactions were observed;” and the abstract: “These vaccines demonstrate no undesirable side effects ...”

Support for new claims 60 and 61 is found in the specification at page 4, lines 13-19, where formalin is listed as an alternative inactivating agent. MPEP 2173.05(i) states:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. *See In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”). *See also Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984).

Since formalin is positively recited in the specification as one of numerous alternative inactivating agents, formalin may be explicitly excluded in the claims.

**Claim objection**

Claim 29 was objected to because it did not end in a period. Claim 29 has been amended to add a period. Therefore, it is respectfully suggested that this objection has been obviated.

The rejections under 35 U.S.C. §112

Claims 21-57 were rejected under the second paragraph of 35 U.S.C. §112. The Office Action stated that the phrase “derived from” in claim 39 makes it unclear what claim 39 refers to. The Office Action did not provide an explanation of why this rejection was also applied to claims other than claim 39.

The Applicants respectfully traverse this rejection. Claim 39 and its dependent claims 40 and 41 are the only claims that contain the phrase “derived from.” This phrase simply indicates the origin of the antigen. That is, the phrase “an antigen derived from another pathogen” in claim 39 means that an antigen is obtained from another pathogen (i.e., other than *Mycoplasma bovis*). This use of the phrase is illustrated in the specification, at page 5, line 20, to page 6, line 3:

In another aspect of this invention, to produce an effective vaccine against *Mycoplasma bovis*, the vaccine must contain antigen derived from a biotype of *Mycoplasma bovis*. Examples of specific embodiments would include vaccines containing antigen derived from *M. bovis* biotypes A, B, or C. In a further specific embodiment, the vaccine comprises antigen derived from more than one *M. bovis* biotypes (e.g., A and B, A and C, B and C, or A, B and C). In a further specific embodiment, the vaccine comprises antigen derived from one or more *M. bovis* biotypes and antigen derived from another pathogen. In a further specific embodiment, the vaccine comprises inactivated or attenuated *M. bovis* biotype A, B or C. In a further specific embodiment, the vaccine comprises at least two inactivated or attenuated *M. bovis* biotypes (e.g., A and B, A and C, B and C, or A, B and C). In a further specific embodiment, the vaccine comprises at least one inactivated or attenuated *M. bovis* biotype with antigen derived from another pathogen. In a preferred embodiment, the vaccine comprises inactivated or attenuated *M. bovis* biotype A, as defined herein, and at least one other biotype of *M. bovis*.

An example of a vaccine comprising “an antigen derived from another pathogen” is provided in the specification, at Example 4, page 17, line 28, to page 18, line 21, where the other pathogen is *Mycoplasma alkalescens*.

Thus, it is clear that claims 39-41 are not indefinite. With respect to any other claims that this rejection is applied to, the Applicants will address the merits of any such rejections

when a reasoned explanation is provided in support of such rejections. Thus, the Applicants request clarification on this matter.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-57 were rejected under the second paragraph of 35 U.S.C. §112. The Office Action stated that the presence of “method steps such as isolating, amplifying, separating and comparing” in claim 47 makes this claim unclear. The Office Action did not provide an explanation of why this rejection was also applied to claims other than claim 47.

Claim 47 has been canceled.

With respect to any other claims that this rejection is applied to, the Applicants will address the merits of any such rejections when a reasoned explanation is provided in support of such rejections. Thus, the Applicants request clarification on this matter.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 53-57 were rejected under the second paragraph of 35 U.S.C. §112. The Office Action stated that “the outcome of the method is different from the preamble” because the claims are drawn to a method of immunizing but the outcome is reducing the incidence of mastitis. The Office Action stated: “The result of the immunizing should be to protect against infection, but the result is reducing the incidence of mastitis.”

The Applicants respectfully traverse this rejection. There is nothing unclear about reciting the reduction of mastitis as an outcome for immunization, since the reduction of mastitis is caused by protection against infection, which the Office Action states is a “result

of immunizing.” Nevertheless, in the interests of expediting prosecution, claim 53 has been amended so that the final clause recites “whereby the bovine animals are immunized so that the incidence of mastitis in the bovine animals is reduced.” This makes even clearer that there is no inconsistency between the preamble and the outcome of claim 53.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The rejection under 35 U.S.C. §102(b)

Claims 21-30, 50, and 52 were rejected as being anticipated by Boothby et al., 1986, Cornell Vet. 76:188-197 (Boothby I).

The Applicants respectfully traverse this rejection. Claims 21-30, 50, and 52 all contain the limitation that “the incidence of mastitis in the bovine animals is reduced.” [emphasis added] Boothby I does not disclose this limitation.

Boothby I used formalin-killed *M. bovis* preparations to treat cows and then challenged some of the quarters (i.e., udders) of the treated cows with live *Mycoplasma bovis*. Other cows were not treated with formalin-killed *Mycoplasma bovis* and served as controls. The amount of *Mycoplasma bovis* infection and inflammation in the challenged and unchallenged quarters of the treated and control cows was then measured. Even assuming that Boothby I’s measure of amount of infection serves as an adequate model of mastitis, Boothby I did not reduce the incidence of mastitis. Boothby I disclosed that there was “little or no difference” in the number of infected quarters between treated and control cows. See page 194, first two sentences, under the heading “Discussion.”

There was little or no difference in number of infected quarters on vaccinated and control cows. Differences did, however, emerge with respect to duration of infection and the inflammatory responses.

As the passage above indicates, Boothby I observed a shorter duration of infection in treated cows, but this observation does not meet the present claims' limitation that the incidence of mastitis must be reduced.

"Incidence" is used in the present application to refer to the number or percentage of cows that show clinical symptoms of mastitis. It is not used to refer to a reduction in the duration of infection in those cows that show clinical symptoms of mastitis, without an accompanying reduction in number or percentage of such cows. The specification illustrates this use of "incidence" at page 19, lines 17-31:

Comparative results were used to measure efficacy of the vaccine. Samples taken from all animals presenting with clinical mastitis were cultured by an independent laboratory to monitor the absence or presence of *Mycoplasma bovis* infection of the mammary gland. Field evaluations were made by comparing clinical incidence of mastitis caused by *Mycoplasma bovis* following herd vaccination to the base line herd incidence prior to vaccination. Results were as follows:

Pre Vaccination Base Line Incidence:

155 confirmed positive clinical *Mycoplasma bovis* infections

Post Vaccination Herd Incidence:

1st year following vaccination:

24 confirmed positive clinical *Mycoplasma bovis* infections

2nd year following vaccination:

1 confirmed positive clinical *Mycoplasma bovis* infection.

This passage describes the results of a field trial of the claimed vaccine. The vaccine was evaluated by counting the number of cows with clinical mastitis before and after vaccination. The numbers of cows so obtained were referred to by the term "incidence." No mention was made of the duration of infections.

This use of the term "incidence" is also seen in the specification at page 21, lines 11-15:

Following vaccination of a significant portion of the herd at Site 1 and Site 2, the incidence of mycoplasma was greatly reduced. From January 1, 2000 to July 18, 2000, there were only 10 animals reported positive for *Mycoplasma bovis* at each site. This reduction in the incidence of *Mycoplasma* positive mastitis cows was regarded as a significant reduction by the operators of Sites 1 and 2.

See also the specification at page 22, line 28 to page 23, line 1:

Following the initiation of the vaccination regime for the herd in February, 2000, a veterinarian monitored the herd for the incidence of *M. bovis*. The dairy reported in September 2000 that there were no confirmed cases of *Mycoplasma* in vaccinated animals, despite the continued challenge from the presence of confirmed, infected nonvaccinated animals.

The Applicants' use of the term "incidence" comports with the plain meaning of that term. Exhibit A is a copy of the entry for the term "incidence" from the Medical Dictionary Online, available at <http://www.online-medical-dictionary.org/omd.asp?q=incidence>. This entry states that "incidence" is "The number of new cases of a given disease during a given period in a specified population." [emphasis added]

Since Boothby I's *M. bovis* preparations did not meet the limitation of claims 21-30, 50, and 52 that "the incidence of mastitis in the bovine animals is reduced," Boothby I's preparation cannot have been the same as the claimed invention and thus does not anticipate claims 21-30, 50, and 52. Therefore, it is respectfully requested that this rejection be withdrawn.

The rejections under 35 U.S.C. §103(a)

Claims 21-31, 50 and 52 were rejected as being obvious over Boothby I in view of Koski et al., 1976, J. Biological Standardization 4:151-154 (Koski).

As discussed above, Boothby I does not disclose the limitation of claims 21-30, 50, and 52 that "the incidence of mastitis in the bovine animals is reduced." Boothby I also does not suggest this limitation, or teach how to obtain this limitation with a reasonable expectation of success. Instead, the teachings of Boothby I failed to achieve this limitation. Therefore, Boothby I does not make obvious claims 21-30, 50, and 52.

Adding Koski to Boothby I does not cure the defects of Boothby I. There is no mention of mastitis in Koski. Accordingly, Koski does not disclose or suggest the limitation that “the incidence of mastitis in the bovine animals is reduced.” Therefore, the combination of Boothby I and Koski does not make obvious claims 21-30, 50, and 52.

Claim 31 depends from claim 30 and adds the limitation that “the *Mycoplasma bovis* biotype has been inactivated by treatment with  $\beta$ -propiolactone.” Koski was cited in the Office Action for the proposition that it was known in the art to inactivate mycoplasmas with  $\beta$ -propiolactone. Therefore, it supposedly would have been obvious to combine Koski with Boothby I in order to arrive at the inactivated *Mycoplasma bovis* vaccine used in the methods of the present invention.

However, it would not have been obvious to combine Koski with Boothby I because:

- Koski’s disclosure is directed to mycoplasmas other than *Mycoplasma bovis*; and
- Koski taught the inactivation of mycoplasmas for reasons other than for the production of vaccines against mycoplasma-caused diseases.

Koski disclosed the inactivation of *Mycoplasma gallisepticum*, *Mycoplasma canis*, and *Acholeplasma laidlawii*. Koski did not disclose the inactivation of *Mycoplasma bovis*.

Koski’s purpose in inactivating mycoplasma was to reduce the level of mycoplasma contamination in vaccines that were directed to other microorganisms, i.e., microorganisms other than mycoplasma. See page 151: “Because the U.S. Department of Agriculture ... requires a test for mycoplasma in vaccines intended for veterinary use it was of interest to establish whether these agents which are used to inactivate vaccines would also inactivate contaminating mycoplasmas.”

Thus, even if it were proper to combine Koski with Boothby I and arrive at the inactivation of *Mycoplasma bovis*, the most that could be arrived at by such a combination

would be the inactivation of *Mycoplasma bovis* contaminants in vaccines directed to other microorganisms. But all the present claims are directed to methods of immunizing bovine animals to reduce the incidence of mastitis caused by *Mycoplasma bovis* in those animals. Nothing in Koski provides a reasonable expectation that inactivating *Mycoplasma bovis* contaminants in vaccines directed to other microorganisms would result in a vaccine that could reduce the incidence of *Mycoplasma bovis*-caused mastitis. Koski does not even mention mastitis. One of ordinary skill in the art would have no reason to use any vaccines produced by the combination of Koski and Boothby I to immunize bovine animals against mastitis and would have no reasonable expectation that the use of any vaccines produced by the combination of Koski and Boothby I would be successful in reducing the incidence of mastitis.

Therefore, even assuming it is proper to combine Koski and Boothby I, this does not cure the defect of Boothby I, i.e., a lack of disclosure or suggestion for the limitation that “the incidence of mastitis in the bovine animals is reduced.” Since all the present claims contain this limitation (including claim 31), Boothby I and Koski do not make obvious claims 21-31, 50 and 52.

Furthermore, additional considerations make it clear that claim 31 is not obvious. The accompanying Declaration of Dr. Joan D. Leonard establishes the following relevant facts:

- The prior art disclosed many possible inactivating agents to choose from in addition to  $\beta$ -propiolactone (§§ 7-9 of the Declaration of Dr. Joan D. Leonard);
- There was no guidance in the prior art as to which inactivating agent might lead to the production of a vaccine that reduced the incidence of mastitis (§ 10 of the Declaration of Dr. Joan D. Leonard); and
- It was surprising that inactivation with  $\beta$ -propiolactone would lead to a vaccine that reduced the incidence of mastitis (§ 15 of the Declaration of Dr. Joan D. Leonard).



In view of this lack of guidance in the prior art with respect to the choice of  $\beta$ -propiolactone as inactivating agent and the surprising effect of  $\beta$ -propiolactone in producing a vaccine that reduced the incidence of mastitis, claim 31 must be viewed as being non-obvious over the prior art.

Furthermore, Dr. Leonard also explained that there was a long felt but unsatisfied need in the art for a *Mycoplasma bovis* vaccine that could reduce the incidence of mastitis. Dr. Leonard cites several publications<sup>1</sup> which indicate that such a vaccine would have been desirable but did not exist prior to the present invention. See the Declaration of Dr. Joan D. Leonard, at ¶¶ 11-14.

In addition to the above considerations, there are further publications that teach away from the present claims and thus indicate that the present claims are non-obvious. Boothby et al., 1986, Can. J. Vet. Res. 50:200-204 (Boothby II)<sup>2</sup>, studied formaldehyde-killed *Mycoplasma bovis*. Boothby II tested whether killed *Mycoplasma bovis* would be effective as a vaccine against bovine mastitis and found that it was not.<sup>3</sup> Thus, Boothby II was unsuccessful. Certainly it must be admitted that failure is a deterrent. The skilled person therefore would have been deterred by Boothby II from attempting to produce inactivated *Mycoplasma bovis* vaccine and thus from seeking the solution provided by the Applicant.

---

<sup>1</sup> These publications cover a period from long before the present invention (1993) to soon after the present invention (2001).

<sup>2</sup> A copy of Boothby II was enclosed with the Information Disclosure Statement filed April 8, 2004.

<sup>3</sup> Despite their prior exposure to killed *Mycoplasma bovis*, the treated cows in Boothby II were not protected against infection (see page 202, middle column: "All experimentally challenged quarters became infected ...").

Moreover, the treated animals in Boothby II showed significant and persistent reductions in the level of milk production. The control cows exhibited a smaller and more transient drop in milk production. See Figure 2 on page 202 for a comparison of treated and control cows. Thus, not only did the killed *Mycoplasma bovis* fail to protect the treated cows, but it caused milk production to be even worse than it would have been had the cows not been treated. Since an important purpose for having dairy herds is to produce milk, the skilled person would certainly be deterred by a result that decreased the production of milk.<sup>4</sup> Given that Boothby II would have deterred the skilled person in two major respects – lack of efficacy and decrease in milk production – Boothby II must be seen as teaching away from the Applicants' invention.

“A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998).

Similarly, in Rosenbusch, 1998, 12<sup>th</sup> International Organisation of Mycoplasma Conference, p. 185 (Rosenbusch)<sup>5</sup>, the administration of inactivated *M. bovis* not only failed to confer protection against respiratory disease but was actually more detrimental than no administration at all. Rosenbusch reported that, following challenge: “A lung lesion score was combined with scores for febrile response and cultural reisolation of challenge to determine if a calf was affected or not. Only 1/5 of sham-vaccinated calves were affected, while 4/5 vaccinated calves were affected regardless of oil adjuvant used.” Such failure to protect, combined with more harm to the vaccinated calves than to the

---

<sup>4</sup> This is recognized by Boothby II at page 200, right column, where it is stated: “If prophylactic vaccination is to be efficacious, it must have minimal effects on the health and productive capabilities of the cow.”

<sup>5</sup> A copy of Rosenbusch was enclosed with the Information Disclosure Statement filed April 8, 2004.

sham-vaccinated calves, would have deterred the skilled person from attempting to make the present invention and thus teaches away from the present invention.

In contrast to Boothby II and Rosenbusch, the Applicants provided an invention which not only prevents disease but also is safe in that it preserves the health and well-being of the vaccinated animals. Most surprisingly, especially in view of prior art such as Boothby II and Rosenbusch, which taught that prior attempts to produce a *Mycoplasma bovis* vaccine led to products that caused unacceptably severe side effects, the vaccine of the present invention does not have a deleterious effect on the vaccinated animals. See the specification, at page 20, lines 1-2: “No injection reactions were observed. No inflammatory udder reactions were observed.” See also the specification, at page 22, lines 20-22: “[T]he vaccinated animals performed well as measured by days to market and rate of gain, both important indicators of a calf’s health and well-being.” Although the specification does not explicitly mention milk production, the skilled person would understand that, since the specification does explicitly state that the vaccinated animals’ “health and well-being” were not detrimentally effected by the vaccine, milk production would not have been compromised.

The Applicants submit that the combination of high efficacy and no deleterious effect on the vaccinated animals’ health and well-being is surprising in view of the prior art’s failure to achieve this combination and leads to the conclusion that the present claims are non-obvious.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-38, 42, 50, and 52 were rejected as being obvious over Boothby I and Koski and further in view of Poumarat et al., 1994, Veterinary Microbiology 40:305-321 (Poumarat).

As discussed above, the combination of Boothby I and Koski does not make obvious claims 21-31, 50, and 52 since the combination of Boothby I and Koski does not disclose or suggest the limitation that “the incidence of mastitis in the bovine animals is reduced.” Poumarat also does not disclose or suggest this limitation. Thus, adding Poumarat to the combination of Boothby I and Koski does not make obvious claims 21-31, 50, and 52.

Claims 32-38 and 42 depend from claim 21 and thus also contain the limitation that “the incidence of mastitis in the bovine animals is reduced.” Therefore, these claims are not made obvious by Boothby I, Koski, and Poumarat for the same reason that claims 21-31, 50 and 52 are not made obvious by Boothby I, Koski, and Poumarat.

In addition, claims 32-38 and 42 contain the limitation that at least two inactivated *Mycoplasma bovis* biotypes are administered. Poumarat was cited in the Office Action for the proposition that would have been obvious to administer at least two inactivated *Mycoplasma bovis* biotypes. The Applicants respectfully submit that this proposition is incorrect. Instead, Poumarat teaches away from the administration of at least two inactivated *Mycoplasma bovis* biotypes.

Poumarat divided *Mycoplasma bovis* isolates into 13 different “genomic groups.” Poumarat then looked at the antigenic variability between and among these genomic groups. Although Poumarat found much antigenic variability, this variability did not correlate with membership in any particular genomic group. In other words, the same amount of antigenic variability could be found within groups as between groups. See page 318, 2<sup>nd</sup> paragraph:

Antigenic profiles of the *M. bovis* strains obtained by immunoblotting with J008 calf serum differed markedly one from the other, the heterogeneity being equally great among strains belonging to the same genomic group and those coming from different genomic groups. There appeared to be no relation between the genomic variability of *M. bovis* and the antigenic variability ...

Because Poumarat teaches that antigenic variability is as great within *Mycoplasma bovis* groups as across *Mycoplasma bovis* groups, Poumarat teaches that there would be no gain in antigenic variability from including more than one type of *Mycoplasma bovis* in a vaccine. That is, there would be no point in having more than one type of *Mycoplasma bovis* in a vaccine. Poumarat thus discourages one of ordinary skill in the art from including more than one biotype in a vaccine and therefore Poumarat teaches away from claims 32-38 and 42.

Poumarat's teaching away is especially pertinent in connection with claim 42. This claim requires that the at least two biotypes be genetically different, as judged by analysis of DNA or RNA. Poumarat teaches that such genetic differences are irrelevant with respect to antigenicity since Poumarat teaches that there appears to be "no relation between the genomic variability of *M. bovis* and the antigenic variability." One of ordinary skill in the art would interpret this as a teaching that nothing is to be gained from including biotypes that are genetically different in a vaccine and thus would be led away from the invention of claim 42.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-38, 42-45, and 47-57 were rejected as being obvious over Boothby I, Koski, and Poumarat, and further in view of Rawadi, 1998, Methods in Molecular Biology 104:179-187 (Rawadi).

As discussed above, the combination of Boothby I, Koski, and Poumarat does not make obvious claims 21-38, 42, 50 and 52 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Rawadi does not disclose or suggest these limitations either. Therefore, adding

Rawadi to the combination of Boothby I, Koski, and Poumarat does not make obvious claims 21-38, 42, 50 and 52.

Claims 43-45, 48-49,<sup>6</sup> and 51, by virtue of their dependencies, also contain the limitations with respect to incidence of mastitis and administration of at least two inactivated *Mycoplasma bovis* biotypes. Accordingly, the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 43-45, 48-49, and 51.

Claims 53-57 contain the limitation with respect to incidence of mastitis and thus the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 51 and 53-57.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-39, 41-45, and 47-57 were rejected as being obvious over Boothby I, Koski, Poumarat, and Rawadi, and further in view of U.S. Patent No. 4,425,330 (Norcross).

As discussed above, the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-38, 42-45, and 47-57 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Norcross does not disclose or suggest these limitations either. Therefore, adding Norcross to the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-38, 42-45, and 47-57.

---

<sup>6</sup> Claim 47 has been canceled.

Claims 39 and 41 also contain the limitations with respect to incidence of mastitis and administration of at least two inactivated *Mycoplasma bovis* biotypes. Accordingly, the combination of Boothby I, Koski, Poumarat, Rawadi, and Norcross does not make obvious claims 39 and 41.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-45, and 47-57 were rejected as being obvious over Boothby I, Koski, Poumarat, and Rawadi, and further in view of Straub, 1991, Comp. Immunol. Microbiol. Infect. Dis. 14:175-186 (Straub).

As discussed above, the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-38, 42-45, and 47-57 because the combination of Boothby I, Koski, and Poumarat does not disclose or suggest the limitations of those claims with respect to incidence of mastitis and/or administration of at least two inactivated *Mycoplasma bovis* biotypes. Straub does not disclose or suggest these limitations either. Therefore, adding Straub to the combination of Boothby I, Koski, Poumarat, and Rawadi does not make obvious claims 21-38, 42-45, and 47-57.

Claims 39-41 also contain the limitations with respect to incidence of mastitis and administration of at least two inactivated *Mycoplasma bovis* biotypes. Accordingly, the combination of Boothby I, Koski, Poumarat, Rawadi, and Straub does not make obvious claims 39-41.

#### New claims

New claims 58 and 59 depend from claims 21 and 32, respectively, and thus are novel and non-obvious. New claims 58 and 59 also recite “the administering does not cause unfavorable reactions.” This limitation is not disclosed or suggested in the prior art. For

example, Boothby I states that “vaccination results in an adverse cellular inflammatory response in challenged quarters” (page 189, 1<sup>st</sup> paragraph). Thus, new claims 58 and 59 are also novel and non-obvious by virtue of this limitation as well.

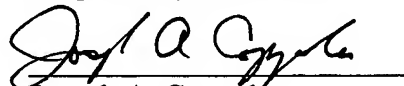
New claims 60 and 61 depend from claims 29 and 32, respectively, and thus are novel and non-obvious. New claims 60 and 61 also recite *Mycoplasma bovis* that has “not been inactivated with formalin.” New claims 60 and 61 are also novel and non-obvious by virtue of this recitation as well.

The time for responding to the Office Action was set for December 14, 2005. Enclosed herewith is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response. Please charge any corresponding fees for the Petition to Kenyon & Kenyon’s Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon’s Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Dated: March 14, 2006

Respectfully submitted,



Joseph A. Coppola

Reg. No. 38,413

KENYON & KENYON

One Broadway

New York, NY 10004

Tel.: (212) 452-7200

Fax: (212) 452-5288